

K201492 Non-Sterile Zirconia BlockMar 10, 2021
279 days to decisionK201492 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k201492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jun 4, 2020
Decision date	Mar 10, 2021
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioden Co., Ltd.
Location	Seoul, KR
Contact	MyeongEun Song
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Med.Com
Contact	Chris Park

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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